

EXHIBIT D

John R. Wagner, M.D.

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON
4 -----:
5 IN RE ETHICON, INC., PELVIC :
6 REPAIR SYSTEM PRODUCTS : MASTER FILE
7 LIABILITY LITIGATION : No. 2:12-MD-02327
8 -----:
9 THIS DOCUMENT RELATES TO ALL : MDL 2327
10 WAVE 6 AND SUBSEQUENT WAVE : JOSEPH R. GOODWIN
11 CASES AND PLAINTIFFS: : US DISTRICT JUDGE
12 :
13 Sylvia Davis :
14 Case No. 2:13-cv-00574 :
15 Laurine Goulette :
16 Case No. 2:13-cv-01776 :
17 Theresa Wilson :
18 Case No. 2:13-cv-00823 :
19 -----

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September 25, 2017

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14 Deposition of JOHN R. WAGNER, M.D.,
15 held at Marriott Melville, 1350 Old Walt
16 Whitman Road, Melville, New York,
17 commencing at 8:30 a.m., on the above
18 date, before Marie Foley, a Registered
19 Merit Reporter, Certified Realtime
20 Reporter and Notary Public.

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<p style="text-align: right;">Page 14</p> <p>1 to cite the articles that you did?</p> <p>2 A. I decided to cite the articles</p> <p>3 that I felt best represented the opinion I</p> <p>4 was trying to make at that point in the</p> <p>5 report.</p> <p>6 Q. And in terms of gathering the</p> <p>7 articles that you reviewed and relied on</p> <p>8 for your report, what was your process for</p> <p>9 that?</p> <p>10 A. My process was to look at the</p> <p>11 articles that I maintained myself. Most</p> <p>12 of the articles that I maintain, with a</p> <p>13 few exceptions, are from the American</p> <p>14 Journal of Obstetrics and Gynecology, the</p> <p>15 OB-GYN Green Journal, the Journal of</p> <p>16 Minimally Invasive Gynecology, the Journal</p> <p>17 of Female Pelvic Medicine and Surgery, and</p> <p>18 then I have a few articles that I maintain</p> <p>19 in my library that I've secured from more</p> <p>20 international journals.</p> <p>21 And then beyond that was added</p> <p>22 by counsel and providing more</p> <p>23 international journal citations that would</p> <p>24 support the opinions that I was setting</p>	<p style="text-align: right;">Page 16</p> <p>1 support the opinions that you're offering</p> <p>2 in this case, as well as find materials</p> <p>3 that did support the opinions?</p> <p>4 A. I think in my --</p> <p>5 MS. KABBASH: Objection to form.</p> <p>6 A. I think in my role as a pelvic</p> <p>7 surgeon, I'm always looking to read</p> <p>8 anything that I can about the subject, and</p> <p>9 sometimes those articles, particularly if</p> <p>10 they're good quality, will change my</p> <p>11 opinion one way or the other. So as a</p> <p>12 function of what I do, I'm always looking</p> <p>13 for more information and more up-to-date</p> <p>14 information and the highest quality data</p> <p>15 that I can get to -- to do the best job</p> <p>16 that I could do in terms of clinically</p> <p>17 treating my patients.</p> <p>18 Q. So, in terms of materials that</p> <p>19 didn't support some of the opinions that</p> <p>20 you're offering in this case, you</p> <p>21 specifically mentioned the Clave study,</p> <p>22 right?</p> <p>23 A. Yes, I did.</p> <p>24 Q. So you'd agree with me that</p>
<p style="text-align: right;">Page 15</p> <p>1 forth.</p> <p>2 Q. Did counsel provide you any</p> <p>3 journals that didn't support the opinions</p> <p>4 you set forth in the report?</p> <p>5 A. There were citations from, let's</p> <p>6 say, Clave talking about mesh properties</p> <p>7 that comes from the international journal</p> <p>8 that don't support the opinions that I put</p> <p>9 forth. There was citations from Otto in</p> <p>10 2003 that don't support the opinions that</p> <p>11 I put forth. But I also provided opinions</p> <p>12 from other sources and citations to refute</p> <p>13 those studies.</p> <p>14 So yes, I was provided with</p> <p>15 studies that don't support my opinions</p> <p>16 necessarily, and I actually have some</p> <p>17 articles, particularly from Cheryl</p> <p>18 Iglesias, in my own library that don't</p> <p>19 necessarily support the opinions that I</p> <p>20 put forth here.</p> <p>21 Q. So, in terms of writing your</p> <p>22 report and forming your opinions, did you</p> <p>23 ever go out and try to find the materials</p> <p>24 and literature out there that didn't</p>	<p style="text-align: right;">Page 17</p> <p>1 there are articles out there in the</p> <p>2 peer-reviewed literature that do not</p> <p>3 support your opinion that polypropylene</p> <p>4 mesh does not degrade, correct?</p> <p>5 A. I think that article is one.</p> <p>6 I'm not sure that I would agree with the</p> <p>7 concept that there's articles. Certainly</p> <p>8 there's not an abundance. I think the</p> <p>9 vast majority of peer-reviewed literature,</p> <p>10 particularly from the major medical</p> <p>11 journals, as well as the opinions from</p> <p>12 major medical societies like AUGS and</p> <p>13 SUFU, don't agree with Clave and his</p> <p>14 conclusions. So, I think there's a vast</p> <p>15 amount of literature that doesn't support</p> <p>16 his opinions, and it's a vast amount of</p> <p>17 opinion from medical societies that I</p> <p>18 subscribe to and respect that don't</p> <p>19 support his opinions.</p> <p>20 Q. And one of the other articles</p> <p>21 that you mentioned is the Iglesias</p> <p>22 article, correct?</p> <p>23 A. Yeah. I don't know if I can</p> <p>24 quote an article on her, but I have some</p>

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1 you didn't go back afterwards and review
 2 Dr. Barbolt's deposition to see who Dr.
 3 Barbolt was and what he testified about?
 4 A. What I testified about or what
 5 he testified?
 6 Q. No, what Dr. Barbolt testified
 7 about.
 8 A. I don't recall doing that.
 9 Q. Okay. Are you aware of whether
 10 or not Dr. Barbolt was in fact a company
 11 designated witness, a person who was
 12 designated to testify on behalf of the
 13 company regarding certain matters?
 14 A. I don't recall. If I ever was
 15 aware, I don't remember it.
 16 Q. Doctor, I'm going to hand you
 17 what's been marked as Exhibit Number 4 to
 18 your deposition.
 19 (Wagner Exhibit 4, Curriculum
 20 Vitae of John R. Wagner, M.D., was
 21 marked for identification, as of this
 22 date.)
 23 BY MR. FAES:
 24 Q. That's just your CV, right?

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1 A. Correct.
 2 Q. Have there been any changes to
 3 the CV since your last deposition in March
 4 of this year?
 5 A. I don't think so.
 6 Q. Is the typo still in there?
 7 A. It probably is.
 8 Q. Now, Doctor, you've actually
 9 published an abstract or article on the
 10 Gynemesh PS mesh in the past, right?
 11 A. I have.
 12 Q. And you know that the Gynemesh
 13 PS mesh is the same mesh that's used in
 14 the Prolift device, right?
 15 A. Correct.
 16 Although I should correct my
 17 previous answer because you said
 18 "published." I don't think I published
 19 it. It was presented at an ACOG meeting
 20 in 2006, I think.
 21 Q. And in that presentation of the
 22 study that you did on 33 Gynemesh PS
 23 patients, you followed those patients for
 24 up to one year, right?

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1 A. Yes. I have to go back and look
 2 exactly, but that's my recollection is
 3 about that time frame.
 4 Q. Did you follow those patients
 5 beyond that time?
 6 A. I'm certain that I did because
 7 they were my patients. I don't think they
 8 were really patients that were referred to
 9 me at the time and I'm certain that I did,
 10 but I did not follow them in an organized
 11 manner. I did not continue the study
 12 beyond that period.
 13 Q. At that one-year follow-up, you
 14 found that 8 of the 33 patients, or 15
 15 percent, had an erosion or extrusion of
 16 mesh of some kind during that follow-up,
 17 right?
 18 A. Yes, that number seems correct
 19 to me.
 20 Q. Just in case you need to refer
 21 to it, I'm going to mark that article as
 22 Exhibit Number 7 to your deposition.
 23 (Wagner Exhibit 7, April 2006
 24 Wagner article "Vaginal Repair of

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1 Symptomatic Pelvic Organ Prolapse
 2 Using Polypropylene Mesh, was marked
 3 for identification, as of this date.)
 4 BY MR. FAES:
 5 Q. Doctor, do you intend to offer
 6 any opinions in this case on what you feel
 7 the overall erosion, extrusion, and
 8 exposure rate of the Prolift mesh is in
 9 patients?
 10 A. I think that I can offer an
 11 opinion based on my experience over the
 12 last 12 years, as well as the reported
 13 experience from others in the
 14 peer-reviewed literature.
 15 Q. And what is the opinion that you
 16 intend to offer?
 17 A. That the mesh erosion rate, and
 18 I'm going to include every type of visible
 19 mesh in that heading, is probably on the
 20 order of about 2 to 5 percent in general.
 21 And there's variation in that based on, I
 22 think, in my opinion, surgical experience
 23 and variation in that as procedures have
 24 been modified over the years.

<p style="text-align: right;">Page 82</p> <p>1 BY MR. FAES:</p> <p>2 Q. Doctor, we're back on the record</p> <p>3 after a short break.</p> <p>4 Are you ready to proceed?</p> <p>5 A. I am.</p> <p>6 Q. So, Doctor, on page 34 of your</p> <p>7 report, you list a known body of potential</p> <p>8 risk and adverse events that are common to</p> <p>9 all forms of surgical treatment of</p> <p>10 prolapse. As you stated, and transvaginal</p> <p>11 mesh is no exception.</p> <p>12 Are you on that page?</p> <p>13 A. Yes, I am.</p> <p>14 Q. So, you list a litany of risks</p> <p>15 and then you state that: "These risks of</p> <p>16 prolapse surgery are widely known by</p> <p>17 surgeons based on their training and based</p> <p>18 on the fact that they are reported in the</p> <p>19 published medical literature."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. Is that an opinion that you</p> <p>23 intend to offer in this case?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 84</p> <p>1 our -- it's part of what we're tested on.</p> <p>2 So, to have a study on something</p> <p>3 that's supposed to be inherent to what you</p> <p>4 know, so you're asking sort of the</p> <p>5 question -- is the question is there</p> <p>6 post-marketing surveillance on whether the</p> <p>7 pelvic reconstructive surgeons have</p> <p>8 learned what they're supposed to have</p> <p>9 learned? Is that what the question is, in</p> <p>10 a way?</p> <p>11 Q. Well, my question is have you</p> <p>12 ever done any kind of study or analysis to</p> <p>13 determine what percentage of pelvic floor</p> <p>14 surgeons did in fact know of all these</p> <p>15 risks in, say, 2012?</p> <p>16 A. Again, that's such a funny</p> <p>17 question.</p> <p>18 No, I've never done a study that</p> <p>19 looks at whether the pelvic floor surgeons</p> <p>20 learned what they were supposed to learn</p> <p>21 about pelvic floor surgery. It just</p> <p>22 doesn't make sense to me, that question.</p> <p>23 Q. So, when you say that they are</p> <p>24 widely known by surgeons, is it your</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. So, is your opinion that these</p> <p>2 risks are widely known by surgeons at all</p> <p>3 times during the marketing of the Prolift</p> <p>4 between 2005 and 2012?</p> <p>5 A. Yes, and again we're talking</p> <p>6 about pelvic reconstructive surgeons,</p> <p>7 surgeons who do this type of surgery, yes.</p> <p>8 Q. Have you done any kind of study</p> <p>9 or analysis to determine what percentage</p> <p>10 of pelvic floor surgeons did in fact know</p> <p>11 of all these risks between 2005 and 2012?</p> <p>12 A. That's a funny question because</p> <p>13 it's an inherent part of the training. I</p> <p>14 mean, if you look at the surgical training</p> <p>15 that we receive as residents and then as</p> <p>16 fellows, people that do this type of</p> <p>17 surgery, this is part of the training.</p> <p>18 It's in the textbooks. It's in, you know,</p> <p>19 Te Linde's Operative Gynecology. The</p> <p>20 complication rates, wound healing, these</p> <p>21 are all subjects that are part of normal</p> <p>22 surgical training. It's in Danforth's</p> <p>23 books on operative gynecology. So it's</p> <p>24 part of our board questions. It's part of</p>	<p style="text-align: right;">Page 85</p> <p>1 opinion that 100 percent of pelvic floor</p> <p>2 surgeons know of all these risks, or not?</p> <p>3 MS. KABBASH: Objection.</p> <p>4 A. I would like to think that my</p> <p>5 field is perfect, but I'm sure it's like</p> <p>6 every other field. There's probably not</p> <p>7 competent people in my field, just like</p> <p>8 there's not competent lawyers and not</p> <p>9 competent firemen and not competent cops.</p> <p>10 But what you're asking is part of our</p> <p>11 inherent training, and so if I -- if I</p> <p>12 could assert the word "competent" and</p> <p>13 "well-trained," then yes, the answer would</p> <p>14 be 100 percent.</p> <p>15 Q. So, it's your opinion that if a</p> <p>16 physician in a particular case testified</p> <p>17 that he didn't know of one or more of</p> <p>18 these risks when he implanted the Prolift</p> <p>19 that that physician wasn't competent?</p> <p>20 MS. KABBASH: Objection.</p> <p>21 A. I'm not sure what risk you're</p> <p>22 referring to because our initial</p> <p>23 discussion was talking about general risks</p> <p>24 of vaginal surgery. So if we're --</p>

<p style="text-align: right;">Page 86</p> <p>1 Q. I'm referring to any of the 2 risks that you have listed in paragraph 1 3 of page 34 of your report. 4 A. Yes, I think that a pelvic 5 surgeon who does pelvic reconstructive 6 surgery realizes that that list of things 7 that I laid out there are potential 8 complications of pelvic repair surgery 9 with or without using mesh. And I would 10 be surprised, and maybe I'm thinking too 11 highly of my own field, that if a board 12 certified urogynecologist in pelvic 13 reconstructive surgery didn't know those 14 things, I would certainly be disappointed. 15 Q. But my question is specifically 16 if a pelvic floor surgeon testified that 17 prior to implanting the Prolift that he 18 didn't know one or more of these risks, 19 would it be your opinion that that 20 physician wasn't competent because he 21 didn't know one or more of these risks? 22 MS. KABBASH: Objection. 23 A. Again, I just go back to my 24 previous answer. I think these are</p>	<p style="text-align: right;">Page 88</p> <p>1 Any surgery causes hematoma. I'd be 2 surprised. 3 I just -- I don't find this list 4 to be that hard. So I would be surprised. 5 Q. Have you made any kind of effort 6 to go out into the medical community or in 7 the literature and actually look at 8 surveys or studies of what physicians 9 actually did or didn't know of these risks 10 to see if your reaction of surprise is 11 justified or if there are in fact many 12 physicians who don't know all of these 13 risks? 14 A. Again, if we're narrowing this 15 down to board certified, fellowship-trained 16 female pelvic reconstructive surgeons, I 17 had be surprised if they weren't familiar 18 with all of these complications with any 19 type of vaginal repair, be it mesh 20 augmented or not. 21 Q. But you haven't specifically 22 studied that issue with regard to what 23 percentage of patients knew or didn't -- 24 MR. FAES: Strike that.</p>
<p style="text-align: right;">Page 87</p> <p>1 general risks that are well-known and I 2 would be surprised. 3 I think competency comes into 4 passing your boards, taking your tests, 5 being approved. Competency is something 6 judged by the board, the American boards, 7 as well as the individual hospitals and 8 their credentialing. But I would be 9 surprised if a board certified pelvic 10 surgeon didn't know those things. 11 Q. Could a reasonable pelvic floor 12 surgeon not know of one of these risks 13 prior to implanting the Prolift? 14 MS. KABBASH: Objection. 15 A. I think these are 16 straightforward risks. 17 Again, I would be surprised. I 18 mean, if you listed ten things and one 19 surgeon somewhere said "I didn't know 20 about urinary retention," I'd be like oh, 21 really? That's pretty common. I'd be 22 surprised. If he didn't know about nerve 23 damage, I'd be like really? I'm 24 surprised. Hematoma, I'd be like really?</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. You haven't specifically studied 2 the issue of what percentage of pelvic 3 floor surgeons did or didn't know of these 4 risks, say in 2005 when the Prolift was 5 launched? 6 MS. KABBASH: Objection. 7 BY MR. FAES: 8 Q. Correct? 9 A. Well, I don't know of a 10 post-marketing surveillance study of 11 doctors. By post-marketing, I mean like 12 I'm saying it almost in jest because it 13 would be post-marketing of their medical 14 training. I just -- I don't know of -- I 15 don't know of any study, and I certainly 16 did not conduct a study to look at my 17 colleagues to see whether they understood 18 the basics of vaginal surgery. I just -- 19 it's a funny question, is my best answer. 20 Q. Would you agree with me that 21 excessive contraction or shrinkage of the 22 tissue surrounding the mesh, vaginal 23 scarring, tightening, and/or shortening is 24 a potential adverse reaction of the</p>

<p style="text-align: right;">Page 98</p> <p>1 have to list all 25 symptoms associated 2 with hematoma.</p> <p>3 Q. Well, you've offered the opinion 4 in this case that the IFU, the 5 professional education materials, and the 6 Prolift surgical guide, and the Prolift 7 surgeon's resource monograph --</p> <p>8 MR. FAES: Strike that. It says 9 accurately, not adequately.</p> <p>10 Q. Would you agree with me that 11 scarring which results in implant 12 contraction is a potential adverse 13 reaction of the Prolift device?</p> <p>14 A. Yes. And again I would quantify 15 that by saying that scarring that results 16 in contraction, with or without an 17 implant, can lead to significant problems.</p> <p>18 Q. Do you think that the fact that 19 there is an implant that actually 20 contracts within the scar presents unique 21 risks in a surgery involving transvaginal 22 mesh as opposed to one that doesn't?</p> <p>23 A. No, I don't think the -- the 24 implant is inert. I don't think the</p>	<p style="text-align: right;">Page 100</p> <p>1 state that you believe that the documents, 2 the IFU, the professional education 3 materials, the Prolift surgical guide, and 4 the Prolift surgeon's resource monograph 5 accurately warn of the potential risk of 6 these devices; is that correct?</p> <p>7 A. Yes.</p> <p>8 Q. Is it your opinion in this case, 9 or are you offering an opinion in this 10 case that the IFU for the Prolift 11 adequately warns of the potential risk of 12 the device?</p> <p>13 A. Okay. I have to give a two-part 14 answer to that.</p> <p>15 First of all, as I read this, I 16 would have to expand this from the use of 17 these slings to include vaginal mesh 18 repairs because I think this was part 19 taken from my TVT expert report. So I 20 would just amend that by adding vaginal 21 mesh repairs in there.</p> <p>22 And adequate to me, again, I 23 think is a function of what the FDA and 24 the regulators want and what the company</p>
<p style="text-align: right;">Page 99</p> <p>1 implant contracts. The scar tissue around 2 the implant can contract and cause 3 contracture that's abnormal, but the 4 implant itself is inert. It doesn't 5 contract.</p> <p>6 Q. So you don't think that implant 7 contraction is a potential adverse 8 reaction of the Prolift mesh?</p> <p>9 A. No, that's not what I said. I 10 said you can have contraction with an 11 implant in it, but the implant's inert. 12 It's not contracting. The scar tissue 13 around it is contracting. So you can have 14 scar contraction with an implant as a 15 complication, but it's not the fault of 16 the implant. It's the scarring.</p> <p>17 Q. Doctor, on page 30 of your 18 report you state that you believe that 19 there's no credible body of evidence 20 published in the medical literature 21 that --</p> <p>22 MR. FAES: Strike that. Let me 23 back up real quick.</p> <p>24 Q. On page 40 of your report you</p>	<p style="text-align: right;">Page 101</p> <p>1 does to follow their guidelines. I don't 2 determine adequacy in terms of the 3 documents. I do think they're accurate, 4 but adequacy is determined by the 5 regulators, company, the FDA, the people 6 that are involved in regulating what 7 should be in an IFU or not.</p> <p>8 Q. So you'd agree with me that you 9 don't have the expertise necessary to 10 offer an opinion as to whether the 11 warnings in the IFU for the Prolift is 12 adequate, just whether they're accurate, 13 correct?</p> <p>14 MS. KABBASH: Objection.</p> <p>15 A. I think that I -- I can speak to 16 the fact that I think they accurately 17 reflect, in my opinion, basic surgical 18 risks involved with implanting the mesh 19 product.</p> <p>20 But again I come back to the 21 definition of "adequate" is really based 22 on what the FDA, the regulators, and the 23 company decide is adequate. I think that 24 the IFU for any product should certainly</p>

<p style="text-align: right;">Page 102</p> <p>1 include risks that are known to occur with 2 that product, but what other risks might 3 be associated with it that might be common 4 knowledge in medical textbooks, amongst 5 surgeons, among the peer review 6 literature, that part of it I think is a 7 gray zone, and whether it's adequate to 8 include some of that or none of that to me 9 is a function of the regulators and the 10 company and the FDA. 11 Q. Do you feel like you have an 12 expertise enough to offer an opinion as to 13 whether the warnings in the IFU for the 14 Prolift in this case are adequate? 15 A. Again, I think they -- again, 16 adequacy is defined by other people, not 17 by me. But I think from a clinical 18 perspective, I found that these warnings 19 accurately warned of the potential use, 20 the risk of the potential use of these 21 slings. I think they were accurate and I 22 felt that they summarized the relevant 23 risk. Whether it's adequate or not is a 24 function of the regulators.</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. Doctor, on page 30 of your 2 report you state that you don't believe 3 that there's any evidence that the Prolene 4 mesh is cytotoxic; is that correct? 5 A. Yes. 6 MS. KABBASH: I'm sorry, which 7 page, 38? 8 MR. FAES: 30. 9 THE WITNESS: 30. 10 MR. FAES: I may have the page 11 wrong. It's 29 into 30. My 12 apologies. 13 So, I guess let me restate the 14 question. 15 BY MR. FAES: 16 Q. You state on pages 29 and 30 17 that you disagree that the Gynemesh PS 18 mesh is cytotoxic? 19 A. I disagree with plaintiff's 20 assertions that it is cytotoxic, yes. 21 Q. Would you agree that one of the 22 potential effects of exposure to a 23 cytotoxic compound is necrotized tissue 24 rounding the mesh?</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. So, can you answer this question 2 for me yes or no: Are you offering an 3 opinion to a reasonable degree of medical 4 certainty in this case that the warnings 5 in the instructions for use for the 6 Prolift IFU are adequate? 7 A. Again, I have to have you define 8 "adequate" for me. 9 Are you talking about basically 10 do they meet the standards of the FDA? 11 Did the FDA and the regulators sign off on 12 them? Because then they're adequate. 13 Do I think from a clinical 14 perspective that they were accurate and 15 summarize the relevant risk? Yes, I do. 16 But adequate is a governmental, regulatory 17 decision. 18 Accurate and reasonable summary 19 of the relative risks is a clinical 20 decision that I can make based on my 21 clinical experience and review of the 22 literature, and I think that they 23 accurately reflected a reasonable summary 24 of the risks.</p>	<p style="text-align: right;">Page 105</p> <p>1 A. No, not necessarily because you 2 could have necrotized tissue from just 3 lack of blood flow, peripheral damage, 4 heat, from cautery, from intrinsic disease 5 such as diabetes. That's why people lose 6 their limbs with diabetes, their legs, 7 their toes get necrotic. So that's not 8 due to mesh. You could have cell death 9 from a lot of sources that's not -- 10 Q. Yeah, I understand all that, 11 Doctor. But my question is is that the 12 tissue turning necrotic is one clinical 13 way that exposure to a cytotoxic substance 14 can manifest itself, right? 15 A. Well, to the exclusion of all 16 the other things that I just said that 17 could potentially be causes. So if you 18 want to exclude every other known cause of 19 necrotic tissue and say have I effectively 20 excluded everything that could cause this 21 and then you're in proximity with 22 something, you have to assume that 23 potentially that could cause it. But 24 again, just proximity doesn't -- doesn't</p>

<p style="text-align: right;">Page 106</p> <p>1 prove anything and it's -- I don't know 2 how you -- I don't know how you'd study 3 the -- I don't know how you'd eliminate 4 all the other causes that could cause 5 necrotic tissue there. So I think 6 clinically that statement is way too broad 7 to accept as blanket, yes.</p> <p>8 Q. Would you agree with me that 9 every time that you'd been asked as an 10 expert witness to examine the safety and 11 efficacy of a mesh device for the 12 treatment of pelvic organ prolapse or 13 stress urinary incontinence you found that 14 that device was safe and effective?</p> <p>15 MS. KABBASH: Objection.</p> <p>16 A. Could you repeat that question 17 again, or have her read that back?</p> <p>18 MR. FAES: I'll just restate it. 19 BY MR. FAES:</p> <p>20 Q. You'd agree that every time 21 you've looked at a mesh device for the 22 treatment of stress urinary incontinence 23 or pelvic organ prolapse as an expert 24 witness you've concluded that that device</p>	<p style="text-align: right;">Page 108</p> <p>1 least the Gore-Tex mesh to you had a 2 complication profile that was unacceptable 3 to you, correct?</p> <p>4 A. Yes, especially for 5 sacrocolpopexies.</p> <p>6 Q. How high would the complication 7 rate need to be on the Prolift before you 8 decide that its complication rate was 9 unacceptable to you?</p> <p>10 MS. KABBASH: Objection.</p> <p>11 A. That's a almost -- there's no 12 rate here. It's almost impossible to -- 13 to put a number like that. This isn't a 14 number -- this isn't a number thing.</p> <p>15 I can tell you that the use of 16 Gore-Tex for sacrocolpopexies was 17 associated in the literature with higher 18 rates of complications than other 19 products, and we have good meta-analysis, 20 good long-term data, high levels of the 21 pyramid data showing complication rates 22 associated with Prolift, and I'm happy 23 with that complication profile, and I 24 think for the appropriate selected</p>
<p style="text-align: right;">Page 107</p> <p>1 is safe and effective, correct?</p> <p>2 A. No.</p> <p>3 Q. In what case did you serve as an 4 expert witness where you found that a mesh 5 device was not safe and effective?</p> <p>6 A. I apologize because I 7 misinterpreted your question.</p> <p>8 In an expert witness capacity, 9 the answer is "yes."</p> <p>10 As a general rule, the answer is 11 "no." There are some implants, 12 classically Gore-Tex was an implant that 13 we used late '80s, early '90s that was not 14 good to neighboring tissues. It didn't 15 allow the appropriate ingrowth and 16 promoted infection and breakdown and 17 erosion.</p> <p>18 So, there are some implants that 19 lend themselves to higher complication 20 rates. But as an expert witness 21 testifying for the meshes that I've been 22 asked to render an opinion on legally, the 23 answer is "yes."</p> <p>24 Q. So you'd agree with me that at</p>	<p style="text-align: right;">Page 109</p> <p>1 patients, it's an excellent procedure, and 2 it was an excellent procedure.</p> <p>3 Q. So, what objective standard are 4 you applying to determine that the Prolift 5 is safe and effective while concluding 6 that the Gore-Tex is not safe and 7 effective?</p> <p>8 MS. KABBASH: Objection.</p> <p>9 A. The objective standard is -- is 10 the objective standards that form my 11 medical opinions: my training, my 12 surgical training, my surgical experience, 13 my teaching, my review of the literature, 14 my attendance at conference, my review of 15 cases presented at conference. The body 16 of medical literature that exists out 17 there is my objective standard. And then 18 as I said in my expert report, rating that 19 body of literature based on quality of 20 evidence is my objective standard.</p> <p>21 Q. So, in terms of complication 22 rate, you'd agree with me that there's no 23 numerical number of complications that you 24 can give me to where you'd feel that the</p>

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<p>1 Prolift device was not safe and effective, 2 right?</p> <p>3 MS. KABBASH: Objection.</p> <p>4 A. I think that there are -- it's 5 hard to separate the individual from the 6 procedure. There were clinical situations 7 where native tissue repairs are 8 appropriate, where mesh repair is 9 appropriate vaginally, where an abdominal 10 mesh repair is appropriate, and I don't 11 think we're trying to pound all patients 12 through the same operation. If there's a 13 surgeon doing only one operation, then I 14 don't think they're serving their patients 15 well.</p> <p>16 You know, it's like -- and in 17 terms of complication rates, you know, we 18 give poisons to people who have cancer 19 because -- because the complication rate 20 of the cancer is much greater than the 21 complication rate of the poison we're 22 giving them. So it's always a measure of 23 what you're treating them versus the 24 complication rate. I wouldn't give</p>	<p>1 were 100 percent, it could potentially be, 2 the Prolift could potentially be safe and 3 effective applying your standard?</p> <p>4 MS. KABBASH: Objection.</p> <p>5 A. Again, I think we're looking at 6 the published literature, the rates of 7 complications as we know it compared to 8 other procedures, including non-treatment 9 and analyzing the patient and her disease 10 process in light of all of that and 11 providing options.</p> <p>12 Q. And there's no numerical 13 standard that you can articulate as you 14 sit here today to where you would 15 determine the Prolift or a device like the 16 Prolift to not be safe and effective?</p> <p>17 A. I don't think of it as just a 18 numerical standard like that.</p> <p>19 MS. KABBASH: Objection.</p> <p>20 A. It's way too broad. It's way 21 too -- it's clinically useless because 22 complications could be anything from, you 23 know, the most minor thing to 24 life-threatening. So you can't even put a</p>
Page 111	Page 113
<p>1 somebody, you know, Cytosan, which is a 2 poison, even if it did treat pelvic 3 prolapse because I have much lower risk -- 4 lower risk treatments for that, but if 5 they have breast cancer, yeah, I'm going 6 to give them that otherwise the breast 7 cancer's going to kill them.</p> <p>8 So, we're always relating what 9 we're treating people with to the 10 underlying disease process and we're 11 looking to benefit the patient overall.</p> <p>12 Q. Well, here we're talking about 13 pelvic organ prolapse and the Prolift.</p> <p>14 A. Right.</p> <p>15 Q. So, how high would the 16 complication rate need to be for a device 17 to treat pelvic organ prolapse before 18 you'd say this isn't acceptable to me, 19 it's not safe and effective?</p> <p>20 MS. KABBASH: Objection; asked 21 and answered.</p> <p>22 A. I agree. I think I've answered 23 it.</p> <p>24 Q. So even if the complication rate</p>	<p>1 number on it 'cause complications could be 2 anything. It's just not a credible -- 3 it's not a realistic way to look at this.</p> <p>4 MR. FAES: I'd love to keep 5 debating, but I think I'm out of time.</p> <p>6 MS. KABBASH: Doctor, I just 7 have a few follow-ups for you.</p> <p>8 EXAMINATION BY</p> <p>9 MS. KABBASH:</p> <p>10 Q. If you could turn to page 45 of 11 your report. It's actually the last page 12 with your signature. And take a look at 13 opinion 8.</p> <p>14 Do you have that, Doctor?</p> <p>15 A. I do.</p> <p>16 Q. You were asked several questions 17 earlier about whether it was your opinion 18 that the warnings and risk information 19 provided in the Prolift materials were 20 adequate.</p> <p>21 Do you remember that line of 22 questioning?</p> <p>23 A. I do.</p> <p>24 Q. Okay. Let me just read into the</p>

<p style="text-align: right;">Page 118</p> <p>1 Q. And you previously testified --</p> <p>2 MS. KABBASH: Strike that.</p> <p>3 Q. You were asked questions about a</p> <p>4 mesh exposure rate with regard to the</p> <p>5 Prolift, and I think that you offered the</p> <p>6 range of 2 to 5 percent.</p> <p>7 Do you recall that?</p> <p>8 A. I do.</p> <p>9 Q. What source were you, source or</p> <p>10 sources, were you basing that on when you</p> <p>11 offered that range?</p> <p>12 A. I think that's just my general</p> <p>13 reading of the medical literature,</p> <p>14 particularly the high quality literature.</p> <p>15 And I also think it reflects a more</p> <p>16 modern -- modern. More recent studies</p> <p>17 because I think that in general, and this</p> <p>18 also correlates with my experience, as</p> <p>19 surgeons get better doing vaginal mesh</p> <p>20 repairs and develop techniques for doing</p> <p>21 vaginal mesh repairs, our erosion rates</p> <p>22 have decreased. So there are erosion</p> <p>23 rates in the literature that go up there,</p> <p>24 they go up like 15, 18, 20 percent, in</p>	<p style="text-align: right;">Page 120</p> <p>1 referenced in the Prolift surgeon's</p> <p>2 resource monograph that was put forth by</p> <p>3 Ethicon?</p> <p>4 A. Yes, I do.</p> <p>5 Q. And what exposure rates are</p> <p>6 provided in that monograph?</p> <p>7 A. Between 3 and 17 percent.</p> <p>8 Q. And in forming your opinions</p> <p>9 about the safety and efficacy of Prolift,</p> <p>10 Dr. Wagner, did you take into</p> <p>11 consideration studies that report exposure</p> <p>12 rates higher than the 2 to 5 percent that</p> <p>13 you discussed before?</p> <p>14 A. Yes.</p> <p>15 Q. If you turn to page 12 of your</p> <p>16 report.</p> <p>17 You were asked some questions</p> <p>18 earlier about the weight of Gynemesh PS</p> <p>19 and specifically I think on what</p> <p>20 information you based your assessment that</p> <p>21 Gynemesh PS was a low-weight mesh.</p> <p>22 Do you recall that?</p> <p>23 A. Mm-hm.</p> <p>24 Q. Do you recall being asked if you</p>
<p style="text-align: right;">Page 119</p> <p>1 that range, but I think that overall it's</p> <p>2 my reading of high quality medical</p> <p>3 literature in conjunction with my</p> <p>4 experience that an experienced pelvic</p> <p>5 surgeon with experience with transvaginal</p> <p>6 mesh probably has a significant erosion</p> <p>7 rate of maybe 2 to 5 percent when dealing</p> <p>8 with vaginal mesh repairs, not slings, but</p> <p>9 vaginal mesh repairs.</p> <p>10 Q. In forming your opinions, did</p> <p>11 you review and consider studies that</p> <p>12 reported mesh exposure rates higher than 5</p> <p>13 percent?</p> <p>14 A. Yes.</p> <p>15 Q. And here in your report on page</p> <p>16 34, do you indicate that occurrence rates</p> <p>17 of mesh exposure are typically under 18</p> <p>18 percent?</p> <p>19 A. Yes.</p> <p>20 MR. FAES: Object to form.</p> <p>21 BY MS. KABBASH:</p> <p>22 Q. If you look at page 35 in the</p> <p>23 last sentence of the top paragraph, do you</p> <p>24 discuss there what exposure rates are</p>	<p style="text-align: right;">Page 121</p> <p>1 could point to a source for that</p> <p>2 information?</p> <p>3 Do you recall that?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Here in your report you</p> <p>6 make the statement: "Gynemesh PS is a</p> <p>7 low-weight Amid type 1 polypropylene</p> <p>8 mesh."</p> <p>9 Is there an article that you've</p> <p>10 cited for that proposition?</p> <p>11 A. Yes, the Jones article.</p> <p>12 Q. And is that the Jones article</p> <p>13 called "Tensile properties of commonly</p> <p>14 used prolapse meshes"?</p> <p>15 A. Yes.</p> <p>16 Q. Was that article published in</p> <p>17 the International Urogynecology Journal?</p> <p>18 A. Yes.</p> <p>19 Q. Is the International</p> <p>20 Urogynecology Journal a peer-reviewed</p> <p>21 publication?</p> <p>22 A. Yes.</p> <p>23 Q. And is that one of the sources</p> <p>24 that you were relying upon for your</p>

<p style="text-align: right;">Page 122</p> <p>1 assessment of Gynemesh PS as a low-weight 2 material? 3 A. Yes. 4 Q. In addition to what you 5 testified to earlier? 6 A. Yes. They describe it as 7 low-weight. 8 Q. You testified earlier in 9 response to questioning from counsel 10 about, I'm paraphrasing this to some 11 extent, but you said that in a healthy 12 woman without certain comorbidities, and 13 in light of the advent of minimally 14 invasive techniques, you would opt to 15 perform an abdominal surgery versus a 16 vaginal surgery to treat prolapse. 17 Did I accurately summarize that? 18 A. I think so, yes. 19 Q. Within the context of your 20 answer, what minimally invasive abdominal 21 surgery are you referring to? 22 A. Using the robotic or 23 laparoscopic approach to do a 24 sacrocolpopexy.</p>	<p style="text-align: right;">Page 124</p> <p>1 the best approach. 2 Q. And why with some patients is 3 Prolift a better alternative to native 4 tissue repair? 5 A. People who are at high risk for 6 recurrence, either based on their family 7 history, their personal health history, 8 such as the history of hernias, people 9 that have already had a vaginal repair 10 that has now failed, people with a global 11 defect across the whole vagina, people who 12 have -- who are of a young age with a 13 family history for prolapse, these are all 14 patients, to list a few, risk factors who 15 are at high risk for failure or recurrence 16 and those are people who may be best 17 served by a mesh augmented repair and not 18 a native tissue repair. 19 Q. I think you also testified that 20 an abdominal sacrocolpopexy is an 21 alternative to Prolift. 22 Is abdominal sacrocolpopexy 23 always a better alternative to Prolift in 24 patients?</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. And what is it about the -- 2 MS. KABBASH: Strike that. 3 Q. At the time that Prolift was 4 introduced to the market, was that form of 5 minimally invasive abdominal surgery, in 6 particular the robotic surgery, available 7 at that period of time? 8 A. If it was, it was only in one or 9 two centers. It was basically in its 10 infancy. Laparoscopic surgery had been 11 around for a while, but there were very 12 few surgeons capable of doing a 13 laparoscopic sacrocolpopexy. 14 Q. You testified earlier that 15 native tissue repairs are an alternative 16 to Prolift. 17 A. Correct. 18 Q. Is a native tissue repair always 19 the best alternative to Prolift for a 20 given patient? 21 MR. FAES: Object to form. 22 A. Never always. It's an 23 alternative. In some people it might be 24 the best approach, but never is it always</p>	<p style="text-align: right;">Page 125</p> <p>1 A. No. 2 Q. And why is that? 3 A. Because you can have patients 4 for whom a sacrocolpopexy is potentially a 5 much more risky procedure based on their 6 medical history, surgical history, their 7 age, their comorbidities, heart disease, 8 and the vaginal approach may make much 9 more sense in that particular patient 10 population. 11 Q. I think you testified in 12 response to one question that you were 13 asked does eliminating trocars eliminate 14 the risk of injury associated with 15 trocars, and I believe you said yes. 16 A. Yes. 17 Q. Is there a downside from the 18 perspective of safety to eliminating 19 trocars such as the trocars used in the 20 Prolift device? 21 A. Yes. I think that if you look 22 at trocar-based repairs, in my opinion, 23 the advantage of the trocar systems, like 24 Prolift, like the Exair, are that you can</p>

<p style="text-align: right;">Page 126</p> <p>1 make smaller incisions, there's less 2 dissection, less need for hysterectomies 3 and other concomitant procedures and 4 allows you to place the mesh in the 5 appropriate compartment in a very 6 minimally invasive way, and by doing it 7 minimally invasively, you minimize local 8 trauma such as bleeding, nerve damage. 9 You minimize pain. You speed the 10 recovery. 11 So, while the actual placement 12 of the trocar is potentially a surgical 13 maneuver that can add a unique risk, the 14 overall benefit of the trocar-based 15 systems is a much lower complication 16 profile and lower morbidity overall. 17 Q. I just have one more area I want 18 to ask you about. 19 You were questioned earlier 20 about what risks were widely known among 21 surgeons, and you were asked if you had 22 performed any study to determine what 23 surgeons actually knew at a given time. 24 Do you recall that line of</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. On the next page, on page 39, do 2 you list studies that discuss the risk of 3 pain with intercourse and sexual 4 dysfunction that were available in the 5 medical literature? 6 A. Yes. 7 Q. And with respect to the articles 8 about pain with intercourse, were these 9 articles that you reference, do they start 10 in 1961? 11 A. Actually, they go back to 1961, 12 yes. 13 Q. And do they go -- 14 MS. KABBASH: Strike that. 15 Q. Doctor, is the published medical 16 literature information that is out in the 17 public and available for doctors to 18 access? 19 A. Yes. 20 Q. And is your review of the 21 published medical literature and the 22 testimony you gave before about what is 23 taught in surgical training the basis for 24 your opinion about what is widely known by</p>
<p style="text-align: right;">Page 127</p> <p>1 questioning? 2 A. I do. 3 Q. Turn to page 38 of your report. 4 In this part of your report, do 5 you have a section called "Commonly Known 6 Risks of Surgery"? 7 A. Yes. 8 Q. Did you perform an analysis of 9 the published medical literature to assess 10 what risks were reported on and available 11 in the publicly available medical 12 literature? 13 MR. FAES: Object to form. 14 A. Yes. 15 Q. Do you discuss studies that 16 discuss the risk of mesh erosion in this 17 section of your report? 18 MR. FAES: Object to form. 19 A. Yes. 20 Q. Do you list here studies that 21 were published between 1997 and 2006 that 22 discuss the risk of mesh erosion? 23 MR. FAES: Object to form. 24 A. Yes.</p>	<p style="text-align: right;">Page 129</p> <p>1 surgeons? 2 MR. FAES: Object to form. 3 A. Yes, including what's in 4 textbooks, which would be part of normal 5 medical and surgical training. 6 MS. KABBASH: I don't have 7 anything else. I think we're done. 8 Thanks, Doctor. 9 (Deposition adjourned at 10:55 10 a.m.) 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

CERTIFICATE

STATE OF NEW YORK
COUNTY OF NEW YORK

I, Marie Foley, RMR, CRR, a
Certified Realtime Reporter and Notary
Public within and for the State of New
York, do hereby certify:

THAT JOHN R. WAGNER, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have
hereunto set my hand this 29th day of
September, 2017.

MARIE FOLEY, RMR, CRR

LAWYER'S NOTES

PAGE / LINE

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This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.